0.45 mm thick and which has a surface formed from removal of an outer layer of the tissue.

29. An expandable jacketed stent comprising a metallic tubular member configured to expand from a first circumference to a second circumference, and a jacket formed of heterologous tissue less than 0.045 mm thick on an outer surface of the stent in a wrapped configuration configured to unwrap as the stent expands.

REMARKS

In the aforesaid Office Action mailed March 22, 2002, the Examiner required a restriction to one of the following inventions:

I. Claims 1-9, 29, 30, and 35-44, drawn to the stent assembly, classified in class 623, subclass 1.13.

II. Claims 10 and 32, drawn to the method of use, classified in class 623, subclass 1.11.

III. Claims 12-20, drawn to the subcombination tissue, classified in class 623, subclass 1.1.

Applicants provisionally elected Group I without traverse and now wish to affirm this election to prosecute claims 1-9, 29, 30, and 35-44.

Claims 1-9, 11, 29, 30, 35-38, and 40-42 are rejected by the Examiner under the judicially created doctrine of obviousness-type patenting as being unpatentable over claims 1-7, 9, 15, 16, 19, and 21-29 of U.S. Patent No. 6,254,627. In response,

applicants have filed concurrently herewith a terminal disclaimer with respect to the '627 patent.

Claims 1-3, 6-9, 11, 29, 35, 38, and 41 have been rejected by the Examiner under 35 USC §102(e) as being anticipated by Winston et al (US 6,117,166). However, applicants believe that the '166 patent is not a valid reference against the present application. Moreover, even if the '166 is a valid reference against the present application, the reference does not teach or suggest each claim feature required by 35 USC §102(e). The present claims are directed to a heterologous stent jacket having a thickness less than 0.45 mm. This and other features are disclosed in applicants original parent application (Ser. No. 08/935,784, filed September 23, 1997). This earlier application predates the filing date of the '166 patent, which has a filing date of October 27, 1997 and applicant believes as a result that the '166 patent is not a valid reference against the present claims..

Claim 11 has also been rejected by the Examiner under 35 USC §102(b) as being anticipated by Narciso (WO 94/15583) and Turi (U.S. Patent No. 5,556,414). However, neither reference teach every feature of the invention defined by claim 11. Specifically, the references do not teach a stent jacket which is formed of heterologous tissue, which has a thickness of less than 0.45 mm and which has an outer layer of the tissue removed.

Claims 29, 30, 38, 39, 40, and 41 are rejected by the Examiner under 35 USC

§102(b) as being anticipated by Love (WO 97/24081). The Love reference fails to teach all of the features set forth in claim 29 and therefore this reference is unable to meet the requirements of 35 USC §102(b). Specifically, this reference does not teach a jacket formed of heterologous tissue less than 0.45 mm thick.

Claims 36, 37, and 42-44 are rejected by the Examiner under 35 USC §103(a) as being unpatentable over Love (WO 97/24081) in view of Winston et al (US 6,117,166). The Love reference does not teach the invention of claim 29 from which these claims depend and the secondary reference Winston et al. fails to make up for the deficiencies of the primary reference. Moreover, the combination fails to suggest the combined features of the rejected claims.

Claim 4 is rejected by the Examiner under 35 USC §103(a) as being unpatentable over Winston et al (US 6,117,166) in view of Love (WO 97/24081). The Winston et al. reference does not teach the invention of claim 1 from which claim 4 depends and the secondary reference Love fails to make up for the deficiencies of the primary reference with respect to claim 4. Moreover, neither reference alone or in combination suggests the utilization of bovine pericardium as required by claim 4, therefore the invention of claim 4 is not obvious as alleged by the Examiner.

Claim 5 is rejected by the Examiner under 35 USC §103(a) as being unpatentable over Winston et al (US 6,117,166) in view of Narciso (WO 94/15583). Neither reference meets the requirements of claim 1 from which claim 5 depends so the proposed combination of references would fail to suggest the invention of claim 5 under

the requirements of 35 USC §103(a).

Applicants have filed herewith a Substitute Specification without the original claims. The substitute specification contains no new matter.

The applicants believe that the pending claims in the present application define patentable subject matter and respectfully request reconsideration and an early allowance thereof. A marked-up copy of the changes made above are attached.

Respectfully submitted,

Edward J. Lynch
Reg. No. 24,422
Attorney for Applicants

Customer No. 23,422

Coudert Brothers LLP
600 Beach Street, 3rd Floor
San Francisco, CA 94109
Direct Dial: (415) 351-5708
Facsimile: (415) 409-7400

CERTIFICATE OF MAILING PURSUANT TO 37 C.F.R. §1.8

I hereby certify that this paper is being deposited in the U.S. Postal Service as first class mail, with sufficient postage addressed to Commissioner for Patents, U.S. Patent and Trademark Office, Washington D.C. 20231, on _____, in San Francisco, CA.

_____

MARKED-UP COPY OF AMENDMENTS

IN THE SPECIFICATION

--RELATED APPLICATIONS

This application is a continuation of application Serial No. 09/156,034, filed September 17, 1998, entitled NON-THROMBOGENIC STENT JACKET, and a continuation-in-part application of application Serial No. 08/935,784, filed September 23, 1997, entitled STENT COVERED WITH HETEROLOGOUS TISSUE [COVER], and application Serial No. 09/005,972, filed January 12, 1998, entitled STENT WITH A BIOCOMPATIBLE NON-THROMBOGENIC JACKET, and application Serial No. 09/053,200, filed April 1, 1998, entitled NON-THROMBOGENIC STENT JACKET, which are incorporated herein in their entirety.--

IN THE CLAIMS

1. (Twice Amended) A stent assembly for maintaining the patency of a body lumen comprising an expandable stent with a cylindrical jacket formed of biocompatible, non-thrombogenic material[, the cylindrical jacket comprising] which has a thinned layer of heterologous tissue less than 0.45 mm thick and which has [having] a surface formed from removal of an outer layer of the tissue.

3. (Twice Amended) The stent assembly of claim [1] 2, wherein the heterologous tissue is a pericardium selected from the group consisting of bovine pericardium[,] and porcine pericardium[, and aortic leaflet, veins and arteries].

4. (Amended) The stent assembly of claim 3, wherein the heterologous tissue comprises bovine pericardium with cross-linked collagen.

5. (Amended) The stent assembly of claim [2] 1 including at least one therapeutic or diagnostic agent releasably contained in the cylindrical jacket.

11. (Twice Amended) A cylindrical jacket formed of heterologous tissue configured to fit over a portion of an intraluminal stent[, the cylindrical jacket] comprising a thinned layer of tissue which is less than 0.45 mm thick and which has [having] a surface formed from removal of an outer layer of the tissue.

29. (Twice Amended) An expandable jacketed stent comprising a metallic tubular member configured to expand from a first circumference to a second circumference, and a jacket formed of heterologous tissue less than 0.045 mm thick on an outer surface of the stent in a wrapped configuration configured to unwrap as the stent expands.